

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS***

2453. Action to enjoin and restrain the interstate shipment of a drug sometimes designated as "The Old Famous Sillard Cancer Remedy." U. S. v. Mrs. Bertha Stephens. Consent decree granting injunction. (Inj. No. 199.)

COMPLAINT FILED: Between September 24 and October 15, 1948, Eastern District of Tennessee, against Mrs. Bertha Stephens, North Chattanooga, Tenn.

NATURE OF CHARGE: That the defendant had been from time to time introducing and delivering for introduction into interstate commerce consignments of a drug consisting of a liquid containing small proportions of tincture of iron and potassium iodide, and sometimes designated by the name *The Old Famous Sillard Cancer Remedy*; that prior to about March 12, 1948, the drug was labeled as follows "The Old Famous Sillard Cancer Remedy Designed for the cure of Cancers or Ulcers and Stomach trouble of any kind. Directions One Tablespoonful before each meal. Made by Mrs. Bertha Stephens (North) Chattanooga, Tennessee"; that on or about March 12, 1948, the defendant caused the drug to be introduced into interstate commerce without any labeling; that the drug for many years past had been and was still intended for use in the treatment of cancers, ulcers, and stomach troubles of all kinds, but that labeling statements revealing its intended uses would be false and misleading, in that the drug was not efficacious in the cure, mitigation, or treatment of such diseases; that any labeling statement representing or suggesting the use of the article as a drug would be false and misleading, in that it was without value in the cure, mitigation, treatment, or prevention of disease, or in beneficially affecting any function of the human body.

The complaint alleged further that prior to March 12, 1948, the drug was misbranded as follows:

Section 502 (a), the name "Cancer Remedy" and the statement "Designed for the cure of Cancers or Ulcers and Stomach trouble of any kind" were false and misleading, since the article would not be efficacious in the cure of such diseases and conditions;

Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient;

Section 502 (f) (2), the labeling of the article failed to bear warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, in that the use of the article might be dangerous to the health of persons suffering from lung disease, chronic coughs, or goiter (thyroid diseases); and the labeling of the article failed to bear any warning against unsafe duration of administration, since it failed to bear a warning to discontinue the use of the article if a skin rash appeared.

The complaint alleged also that the article when introduced into interstate commerce on or about March 12, 1948, was misbranded as follows:

Section 502 (f) (1), the article failed to bear adequate directions for use for the purposes for which it was intended;

Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in pathological conditions where its use may be dangerous to health, and warnings against unsafe duration of administration, in such manner and form as are necessary for the protection of users;

Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor;

Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

Section 502 (e) (2), the article failed to bear a label declaring the common or usual name of each active ingredient.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined during the pendency of the action, and permanently, from shipping the above-mentioned drug in interstate commerce.

*See also No. 2452.

DISPOSITION: October 15, 1948. The defendant having consented to the entry of a decree, an order was entered enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce the above-mentioned product, which was misbranded within the meaning of Sections 502 (a), 502 (f) (1) and (2), 502 (e) (2), and 502 (b) (1) and (2).

2454. Misbranding of Formalon Cream. U. S. v. Daniel Platt (Formalon Company). Plea of guilty. Defendant fined \$3,000, given suspended sentence of 3 years in jail, and placed on probation for 3 years. (F. D. C. No. 21466. Sample Nos. 70802-H, 12947-K, 12948-K.)

INFORMATION FILED: January 23, 1948, Southern District of New York, against Daniel Platt, trading as the Formalon Co., New York, N. Y.

ALLEGED SHIPMENT: From the State of New York into the States of Delaware, California, Pennsylvania, Massachusetts, and New Jersey. The product was shipped during March and April 1946, and January and March 1947, and a circular letter was shipped during March, April, and November 1946, and January and March 1947.

PRODUCT: Analysis disclosed that the product consisted of a pale-yellow semisolid containing 27.2 mg. diethylstilbestrol in each 2 ounces. Examination showed that the circular letter contained a number of statements relating to the efficacy of the product for the development of the breasts and pictures of women purportedly before and after the use of the product.

LABEL, IN PART: "Directions Apply $\frac{1}{2}$ teaspoon of Formalon daily to each breast and massage gently at bedtime, or as otherwise directed by physician. Formalon Cream."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and pictures appearing in the circular letter were false and misleading. The statements and pictures represented and suggested that the article would be effective to develop the breasts of women, whereas it would not be effective for such purposes.

Further misbranding, Section 502 (a), the before and after pictures designated "Case 5469" and the statement underneath "showing breast growth produced after using Formalon 8 weeks" and the before and after pictures designated "Case 1721" and the statement underneath "showing breast growth produced after 12 weeks of applying Formalon Cream," appearing in the circular letter, were false and misleading. The pictures and statements represented and suggested that the pictures were pictures of women which had been taken before and after treatment with the article, whereas the pictures were pictures of women which had been taken before and after treatment with another drug.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the directions which appeared on the label failed to reveal the conditions for which the article was to be used.

DISPOSITION: August 4, 1948. A plea of guilty having been entered, the court fined the defendant \$3,000 and sentenced him to serve 3 years in jail. The jail sentence was suspended and the defendant was placed on probation for 3 years, conditioned that he should not directly or indirectly engage in the sale of drugs or food preparations of any kind, nature, or description.

2455. Misbranding of Emerson's Medicine, Emerson's K-A-C Cough Syrup, and Emerson's Lightning Liniment. U. S. v. 7 Bottles, etc. (F. D. C. No. 24854. Sample Nos. 22544-K to 22546-K, incl.)

LIBEL FILED: On or about May 27, 1948, Southern District of Texas.

ALLEGED SHIPMENT: By the Emerson Medicine Co., from Kansas City, Mo.; the products were shipped on or about April 8, 1948, and a number of circulars were shipped on or about January 5, 1948.

PRODUCT: 7 12-ounce bottles of *Emerson's Medicine*, 7 2-ounce bottles of *Emerson's K-A-C Cough Syrup*, and 18 2-ounce bottles of *Emerson's Lightning Liniment* at Houston, Tex., together with 32 circulars entitled "Emerson's Medicine," which were enclosed with the syrup and wrapped around the bottles of the liniment, and 50 circulars entitled "Emerson's Medicine is Mother Nature's Own Laxative Medicine," which were shipped separately from the products.

Analyses disclosed that the *Emerson's Medicine* consisted of water and extracts of plant drugs, including a laxative drug, together with a small propor-